

User Manual



MAJ 23/10/2014 UK



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A. GENERAL

IMPORTANT INFORMATION FOR PATIENTS AND THEIR FAMILIES

This product helps to prevent and treat bedsores

Why have you been prescribed this?

Your condition reduces your mobility and exposes you to the risk of bedsores.

What is a bedsore?

A bedsore is a lesion on the skin which can be deep or shallow and is caused by excessive and prolonged compression of tissue between the body and a support. This excessive pressure can stop blood circulation and cause bedsores.

There are several types of bedsore: simple redness lasting longer than a day, hardening of the skin, or a deep or shallow wound which in serious cases can affect muscles or underlying bone.

A bedsore may be related to reduced mobility and/or a chronic disease.

How does this support work?

This support reduces pressure and allows better blood circulation in skin, thereby helping to prevent bedsores.

Directions and precautions for use:



A support is not enough in itself to prevent bedsores; other preventive steps are also required:

- change position frequently (at least every 2 to 3 hours)
- keep skin clean and avoid soaking
- if incontinent, replace protection regularly
- check skin condition daily or have someone else check it
- have a proper diet
- drink regularly and sufficiently

If any of these steps cannot be followed, you must inform your doctor or nurse as early as possible.

Report any abnormal events to your doctor or nurse such as fever, pain or redness or whitening of pressure points (head, shoulder, back, hip, shoulder blade, pelvis, heel, etc).

It is important not to have too much thickness between the body and the support, except for a cover for the bed support, clothing and potentially a complete change. Wear loose cotton clothing preferably and if possible with no closures around the pressure area. Do not insert folded towels or sheets, cushions, etc.

Ensure there are no foreign objects such as piping, crumbs, etc.

For hygiene reasons, each bedsore preventive aid must be for one person only.

B. PACKAGE CONTENTS

- 1 rolled mattress in a carrier bag
- 1 pump (located inside the rolled mattress)
- 1 electrical cable
- 1 user manual
- 1 Dirty/Clean label

C. PICTURE LEGENDS

	See the User Manual and (or) instruction leaflet
	Warning. Important safety information.
	Store in a dry place.
	Category II device (Double insulation)
	Warning, electrical and electronic equipment with collective waste collection
	BF type electrical device - Protect against electrocution.
	Complies with requirements of European directive 93/42/CEE applicable to medical devices
	Alternative current
	Risk related to electrical current

D. DESCRIPTION

The mattress has 18 air cells that are 12 cm high on a 5 cm foam base.

The mattress is connected to a pump that blows filtered air at an inflation pressure set according to the patient weight and according to his/her position in the bed.

The cells are interconnected and have 2 networks inflated alternately, i.e. one out of two.

The whole thing is protected by an integral removable waterproof, breathable cover.

E. METHOD OF OPERATION

- Alternating pressure avoids prolonged vascular compression likely to cause tissue hypoxia.
- Pressure adjustment means that the mattress can be adapted to the patient's morphology and his/her position.

F. INDICATIONS

Prevention* of bedsores in pressure areas, for individuals confined to bed for more than 15 hours with a moderate to high risk of bedsores(s) assessed according to a validated clinical scale.

Bedsore treatment aid for stage 1 to stage 2 bedsores in pressure areas with medical advice.

*According to opinion of National Medical Devices Evaluation Commission (Ex-CEPP) published in JORF on 21 July 2005 - amended in July 2006 - and in accordance with clinical expert opinions.

G. CONTRAINDICATIONS

Patients over 110 kg

Use as hyperbaric chamber. Use on stretcher.

H. PRECAUTIONS

Unstable bone injuries and/or muscle injuries in contact with the support. Cervical pain combined with strict bed confinement.

Initial post-surgery days for bedsores (skin graft or strips)

Patient treated at home unable to have medical assistance or a third person

Bed confined individuals with thoracic-abdominal corset

Individuals requiring continuous posture combining chest levator over 40° and lower limb levator over 20°

Behavioural changes in person being treated (mood disorder, discomfort, etc.)

Use of direct physical supports on strict medical prescription, re-assessed every 24 hours by following the following methods:

1. Inflate the mattress using the rapid inflator for a firm surface, or adjust the potentiometer to weight 110 kg
2. Attach the connections to the fixed bed base
3. Select the corresponding weight for the person by turning the potentiometer.
4. Check the pressure of support connections several times a day.

WARNING:

- In accordance with appendix I of directive 93/42/CEE covering essential requirements applicable to medical devices, only compatibility between systems assembled by **ASKLÉSANTÉ** guarantees safe assembly for the use of the AXTAIR motorised air mattress.
- The description and performance of the motorised air support will be exclusively maintained by the use of the AXTAIR ONE pump (ref. VAXT/POMPE/ONE or VAXT2/POMPE/ONE) combined with the AXTAIR ONE mattress (ref. VAXT/MA/ONE or VAXT2/MA/ONE) and optional inflation/deflation kit (ref. VKIT/AXT).
The national health authority can take appropriate steps at any time to check the marketing conditions for products and take the necessary steps in the event of danger or non-compliance with regulations. Should the usage requirements listed above not be complied with, the user's responsibility is likely to be at cause in the event of an accident.
- The Axtair One pump is a pressurized device (AP) generating pressure whose level presents no risk to users and the equipment.
- The Axtair One pump is a device in permanent operation. In the event of an emergency, it can be switched off by unplugging the cable from its base.
Only accredited and competent staff can repair or interfere with the inside of the device on condition that the cable is disconnected from the electricity network.
- The Axtair mattress is placed directly on the medical bed base. Use under an overmattress is the sole responsibility of the installer.
- Usage temperatures must be between 10°C and 40°C.
- The product must not be used at altitudes over 2000 m.
- The device must be used in an electromagnetic environment in which radiated RF disturbances are controlled (see section Q)

I. DESCRIPTION

SUPPORT DESCRIPTION
Validated user weight: 30 – 110 kg
Support weight: 5.7 Kg.
Support size: - VAXT/MA/ONE: 195 x 85 x 17 cm - VAXT2/MA/ONE: 195 x 87 x 17 cm
Height of air cells: 12 cm
Rapid CPR deflation in less than 15 seconds.
Cell material: Ether polyurethane 300 µm
Polyether 18 kg/m3 foam base (optional cover with a PROMUST PU cover: THIP/AXT/MS)
Upper section of cover: PROMUST PU (Jersey/Polyurethane) (optional Promust CIC)
Lower section of cover: PU/PVC non-slip (polyurethane/Vinyl polychloride)
Standby with transport cap: > 8 hours
Compliance with inflammability tests according to: EN 597-1&2: 1995; GPEM DI-90 & DI-89bis
Cover and foam base guarantee: 1 year (does not replace legal guarantee) Promust CIC cover guarantee: 2 years
Life span: 5 years (not cover)
Compatible with the rapid VKIT/AXT inflation pump
Mattress traceability: The date written on the label of the mattress cover is the date of mattress manufacture.

PUMP DEVICE DESCRIPTION
Alternating mode: 1 cell out of 2
Cycle time: 6 minutes
Inflation pressure adjustment depending on the patient's position
Mattress inflation time: less than 30 minutes (or less than 2 minutes with the rapid VKIT/AXT inflater)
Removable anti-particle filter
Acoustic power: < 35 dBA (according to NF EN ISO 3744: 1995)
Electricity supply: 230V 50Hz
Electrical cable length: 4.2 m
Average power consumption: 8 Watts. Max power: 10 VA
Fuse: T0,63A L35A 250V 5x20
Class II electric shock protection.
Electrical and Electro Magnetic conformity according to CEI 60601-1: 2005 and 60601-1-2: 2007
Legal guarantee: 2 years
Life span: 3 years
Pump traceability: the number on the back of the pump is a unique identification number.
PUMP DESCRIPTION: (indicative values)
- Max flow : > 7 litres / min
- Pmax : > 150 mBar

J. AXTAIR ONE CONTROL PANEL**Power indicator light**

This orange light, which is permanently displayed, shows that the pump is connected to electricity (electric energy source), even if the pump is not switched on.

**Pressure adjustment potentiometer**

This potentiometer adjusts the internal pressure of the mattress cells. Its notching principle ensures that the selection is maintained regardless of circumstances (touch, vibration, etc.)

K. INSTALLATION / USE

1. Unroll the mattress on the bed base according to the instructions given by the "head" and "foot" symbols printed on the surface of the cover.
2. Hang the pump on the bed panel (feet side) using the brackets and attach them.
3. Guide the cable for the pump to the nearest plug socket and plug it in. The orange light comes on and the pump starts automatically.

Recommendation: Use the optional ASKLE SANTE rapid inflation pump:

- Connect the electrical cable for the inflation pump to the electricity
- Block the electricity cable for the mattress with the adjoining cap.
- Turn the CPR valve to OPEN.
- Connect the rapid inflation pump as per the diagram opposite.

(Note: the pump inflates in one direction and deflates in the other).

- Press and hold the on button until the mattress is inflated (approx. 2 minutes)

4. Turn the CPR valve of the mattress to the CLOSE position
5. Connect the electricity cable for the mattress to the pump connector
6. Lie the patient down on the mattress if you think it is sufficiently inflated.
7. Adjust the inflation pressure for the mattress to the weight of the patient using the weight scale.

Adjustment of pressure for semi-sitting position i.e. incline of chest levator of bed > 45°:

To avoid the risk of pressure of buttock areas on the foam mattress in semi-sitting position, the internal pressure of cells must be increased.

We recommend increasing the pressure by 1 notch.

- Example 1 - A 50 kg patient in sitting position would need a pressure equivalent to a 60 kg patient in lying down position.
- Example 2 - For a 110 kg patient, adjust the setting according to the person's position

Lying down position ($\leq 45^\circ$)



Semi-sitting position ($> 45^\circ$)



The pump's instructions for use are written on the right side of it.



The weight scale is indicative. Check there is no scraping and increase the pressure by one notch, if required. For comfort, inflation can also be adjusted up or down. The electrical cable must be installed in such a way as to avoid any interference with articulated parts, the wheels of the bed, the use of the hoist, and staff moving around the bed. The mains plug, the pneumatic connector and the CPR valve must be permanently visible and accessible. When working on the fuse, the electricity cable must be disconnected from the pump.

L. ALARM

In the event of an **electrical failure alarm**, the power light goes off.

1. Check that the compressor is still connected to the pump and/or to the socket and/or that the general electricity circuit is compliant and that the power light is on.
2. If the problem continues, we strongly recommend that you disconnect the air pipes from the compressor, block them with the "transport" cap and regularly move the patient (change position every 2 to 3 hours)
3. Should the device stop working, contact your retailer.

Note: correcting the fault results in the power light coming back on.



Should the mattress be accidentally deflated, when re-inflating, check that the patient's limb is not stuck between the mattress and the bed barriers.

CPR (Emergency Cardio Pulmonary Resuscitation)

In the event of a heart attack:

1. Turn the nozzle of the CPR valve to position the plastic tube to the "OPEN" position.
2. The mattress deflates and the lower part of the thorax can be found in less than 15 seconds on the firm side of the bed base to enable External Cardiac Massage.



The mains plug, the pneumatic connector and the CPR valve must be permanently visible and accessible.

M. MAINTENANCE/DISINFECTION

The method used depends on the level of disinfection required; Techniques and products will be used according to validated good practice recommendations. See the diagram at the end of this section



- Daily maintenance of the compressor is done when it is switched on and with the mattress connected to the connector. By default, the electrical cable connected to the compressor must be unplugged. The orange light must be off.
- Do not use a high pressure jet to clean an Axtair One compressor.
- Do not put the compressor on bare ground. Hang it ≥ 60 cm away from a water point.



Prohibit the use of corrosive cleaning products such as industrial spot removers, acetone solvents, ether and colorant products (iodized alcohol, potassium permanganate, silver nitrate, etc). Prohibit abrasive materials such as steel wool or "scotch brite".

The filter should be changed 1 time per year or more frequently depending on environmental conditions (dust, smoke, ...).

Compressor:

Use a microfibre dish cloth soaked in a surface detergent/disinfectant* at the manufacturer's recommended concentrations. Comply with application time.

The filter must be changed at least every 6 months or more frequently depending on environmental conditions (dust, smoke, etc.)

Mattress:

Use a microfibre dish cloth soaked in a surface detergent or Detergent-Disinfectant* at the manufacturer's recommended concentrations. Rinse. Use a surface Detergent-Disinfectant product. Comply with application time.

* CE marking obligatory under terms of directive 93/42/CEE for products claiming use on surfaces of Medical Devices. Use products that comply with biocide directive.



Maintenance recommendations for the cover and base



Wash in water, max temp 90°C, reduced mechanical action, rinsing in decreasing temperature, reduced wringing out.



5000 ppm chlorine authorised. (1000 ppm in standard use)



Ironing forbidden.



Dry cleaning forbidden, use of solvent-based stain remover forbidden.

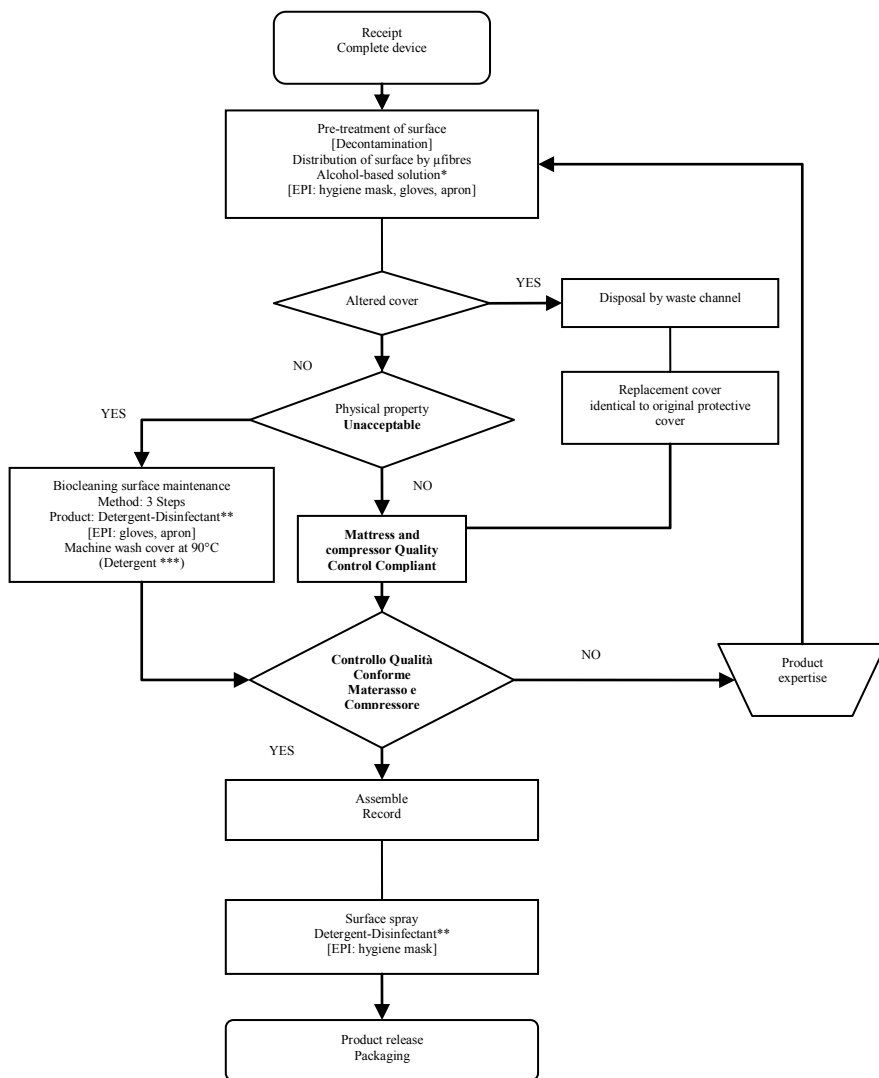


Drum drying authorised, moderate temperatures

Item treated with a biocidal substance that is safe for the user. www.winnicare.fr

The MANUFACTURER will make available, upon request, the circuit schemas, list of components, descriptions, calibration instructions or any other information relevant to MAINTENANCE STAFF to carry out authorised repairs in accordance with the contract that binds the requester to the ASKLÉSANTÉ manufacturer.

Recommended maintenance and disinfection schema



* Broad spectrum alcohol-based disinfectant cleaner, standardised: bactericide EN1040, EN13727, Fungicide EN1275, EN13624, NF T72-190, Sporicide EN13697, EN14561, Polyvirus EN14476, HBV, HCV.

Limit spraying onto cells

** Detergent-Disinfectant for maintenance of floors and surfaces (Positive list of Disinfectants)

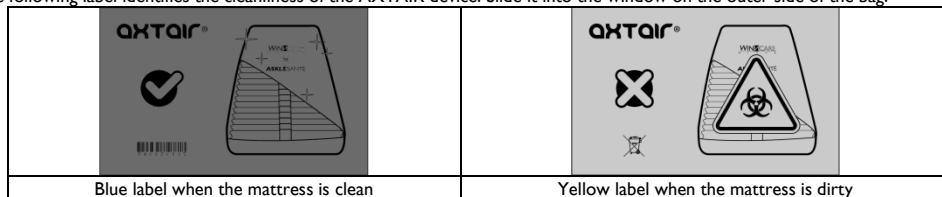
*** Neutral detergent (domestic washing product)

N. STORAGE

A bag is provided for transport and storage of the mattress, which must be rolled. Removal of air from the mattress can be facilitated by using the inflation/deflation pump connected to the CPR (OPEN position).

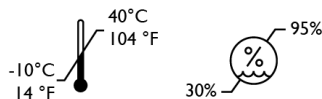
The compressor can be put inside the bag, in the rolled mattress.

The following label identifies the cleanliness of the AXTAIR device. Slide it into the window on the outer side of the bag.



Temperature conditions:
Hydrometry level conditions:

mini: -10°C or 14 °F; maxi : + 40°C or 104°F
mini: 30% ; maxi : 95%



Keep devices away from humidity, direct sunlight, heat. Prevent the risk of shock or alteration by spiky or sharp objects.

O. DISPOSAL OF MEDICAL DEVICE**PROTECTION OF THE ENVIRONMENT**

This device contains several recyclable materials.

This symbol shows that this equipment is recyclable and that used devices must not be mixed with other waste.

Recycling of devices will therefore be done under the best safety conditions to limit the effects on the environment and

human health in the event of the existence of dangerous substances, in accordance with the European directive 2002/96/CE for obsolete electrical and electronic equipment.

You can contact the shop, retailer or distributor from whom the product was purchased to find out about collection points for used devices closest to you.

Before disposal, the device should be cleaned in accordance with the MAINTENANCE-DISINFECTION* instructions to avoid any risk of contamination. Thank you for helping to protect the environment.

P. WARRANTY

The mattress has a 2 year guarantee - except for the cover and foam base* - and the compressor from the receipt of the purchased good. The warranty covers faults or hidden defects and the non-compliance of the supplied product.

The warranty does not apply to the compressor if the seals under the instruction label are removed and/or in the event of improper use of the product or non-compliance with maintenance recommendations.

To benefit from it, the invoice for the product purchase must be kept.

Contact your distributor or pharmacist.



In the event of removal of guarantee seal, ASKLE could refuse to cover repair and authorise the right to end this.

* The cover and foam base are guaranteed for 1 year.

Q. ELECTROMAGNETIC DATA

Axtair One is designed for use in the electromagnetic environment specified below. The customer or user of the Axtair One should ensure that it is used in such an environment.

Electromagnetic emissions		
Emissions test	Conformity	Electromagnetic environment - Directives
RF emissions CISPR 11	group 1	The Axtair One uses RF energy only for internal operations. Consequently, its RF emissions are very low and are not likely to cause interference to a nearby electronic device.
RF emissions CISPR 11	class B	
Harmonic emissions CEI 61000-3-2	class B	
Pressure fluctuations/Flickering CEI 61000-3-3	Compliant	The Axtair One is suitable for use in all facilities, including domestic ones and those directly connected to low voltage public electricity network supplying domestic premises.

Electromagnetic immunity			
Immunity test	Test level CEI 60601	Level of compliance	Electromagnetic environment - Directives
Electrostatic discharge (DES) CEI 61000-4-2	± 6 kv on contact ± 8 kv in air	± 6 kv on contact ± 8 kv in air	Floors should be wooden, concrete or ceramic tiles. If floors are covered in synthetic materials, the relative humidity should be at least 30%.
Rapid transitions into salvo CEI 61000-4-4	± 2 kv for electrical supply lines ± 1 kv for input/output lines	± 2 kv AC or DL supply input ± 1 kv signal line and interconnection	The quality of the electrical supply network must be that of a typical commercial or hospital environment.
Transitory excess voltage CEI 61000-4-5	± 1 kv between phases ± 2 kv between phases and earth	± 1 kv in differential mode ± 2 kv in common mode	The quality of the electrical supply network must be that of a typical commercial or hospital environment.
Weak voltage, brief power cuts and voltage variations on electricity supply lines CEI 61000-4-11	< 5% UT (>95% weak UT) for 0,5 cycle 40% UT (60% weak UT) for 5 cycles 70% UT (30% weak UT) for 25 cycles < 5% UT (>95% weak UT) for 5s	0% (residual voltage) over 0,5 period 40% (residual voltage) for 5 periods 70% (residual voltage)	The quality of the electrical supply network must be that of a typical commercial or hospital environment.
Magnetic field at frequency of electricity network (50/60 Hz) CEI 61000-4-8	3 A/m	3 A/m at 50 Hz	The magnetic fields at the frequency of the electricity network should have the levels characteristic of a representative site located in a typical commercial or hospital environment.
RF disturbances CEI 61000-4-6 Radiated RF disturbances CEI 61000-4-3	10 veff of 150 khz at 80 MHz 3V/m of 80 mHz at 2,5 GHz	10 V 3 V/m	Portable and mobile RF communication devices must not be used near any part of an Axtair One, including cables that of the recommended separation distance, calculated from the equation applicable to the emitting frequency. Recommended separation distance: $d = [3,5 / V] \sqrt{P}$ $d = [3,5 / E] \sqrt{P}$ 80 MHz at 800 MHz $d = [7 / E] \sqrt{P}$ 800 MHz at 2.5 GHz Where P is the maximum output power of the emitting device in watts (W), according to the manufacturer of the emitting device and d is the recommended separation distance in metres (m). The field intensities of fixed RF emitters, determined by an electromagnetic test on site, should be lower than the conformity level in each range of frequencies.
NOTE 1 : UT is the voltage of the alternative network before the test level is applied. NOTE 2 : At 80 MHz and at 800 MHz, the highest frequency range applies. NOTE 3 : These directives may not apply in all situations. The electromagnetic propagation is affected by absorption and by reflection of structures, objects and people.			
The field intensities of fixed emitters, such as base stations for radiotelephones (cellular/cordless) and terrestrial mobile radios, amateur radio, AM and FM radio and TV, cannot be theoretically planned with accuracy. To evaluate the electromagnetic environment due to fixed RF emitters, an electromagnetic test should be considered on this site. If the field intensity, measured at the location where the Axtair One is used, exceeds the applicable RF conformity level below, the Axtair One should be monitored to check that it is working normally. If abnormal performance is found, additional actions may be required, like redirecting or repositioning the Axtair One. For the frequency range of 150 KHz at 80 MHz, the field intensities should be below $[V] \sqrt{P}$ V/m.			

Recommended separation distances between portable and mobile RF communication devices and the Axtair One

The Axtair One is planned for use in the electromagnetic field in which radiated RF disturbances are controlled. The customer or user of the Axtair One can help to prevent electromagnetic interference by maintaining a minimum distance between portable or mobile RF communication devices (emitter) and the Axtair One, as recommended below, according to the maximum emission power of the communication device.

Maximum output power assigned for the emitter W	Separation distance according to frequency of emitter		
	of 150 kHz at 80 MHz $d = [3.5/V] \cdot \sqrt{P}$	80 MHz at 800 MHz $d = [3.5/E] \cdot \sqrt{P}$	of 800 MHz at 2.5 GHz $d = [7/E] \cdot \sqrt{P}$
0.01	0.04	0.12	0.23
0.1	0.11	0.37	0.74
1	0.35	1.17	2.33
10	0.11	3.69	7.38
100	3.5	11.67	23.33

For emitters whose assigned maximum emission power is not given above, the recommended separation distance d , in metres (m) can be estimated by using the equation applicable to the frequency of the emitter in watts (W), according to the manufacturer of the latter.

NOTE 1 : At 80 MHz and 800 MHz, the separation distance for the highest frequencies range applies.

NOTE 2 : These directives may not apply in all situations. The electromagnetic propagation is affected by absorption and by reflection of structures, objects and people.

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